Executive Summary
Direct Investigation Report

Government's Mechanism for Monitoring Vaccines Provided by Private Healthcare Facilities

Introduction

Advances in medicine have brought us more and more vaccines against diseases such as diphtheria, measles, pneumonia and influenza, etc. In recent years, a much talked-about vaccine is the human papillomavirus ("HPV") vaccine. In Hong Kong, some vaccines have been included in the Government's Vaccination Schemes and members of the public can receive scheduled vaccinations as they grow up. For vaccines not included in the Schemes, people can make their own arrangements according to their need and wish for vaccination.

2. Vaccines enter the human body through either injection or oral administration. Vaccines of defective quality would, therefore, directly affect or even jeopardise the health of those who are administered the products. Proper monitoring of vaccines by the Government is of paramount importance.

3. In mid-2019, there had been media reports that some private healthcare facilities ("PHFs") were suspected of providing defective nine-valent HPV vaccines. The Department of Health ("DH") and the Customs and Excise Department ("C&ED") subsequently took joint actions and uncovered counterfeit HPV vaccines in some PHFs. This had aroused public concern over the effectiveness of the Government's monitoring of vaccines.

4. This direct investigation, covering the Food and Health Bureau ("FHB"), DH and C&ED, aims at examining the Government's mechanism for monitoring vaccines provided by PHFs and exploring room for improvement, if any, as well as enhancing public understanding of the Government's monitoring efforts.

Our Findings

5. This Office has the following findings and comments with regard to the Government's mechanism for monitoring vaccines

provided by PHFs.

(I) Quite Comprehensive Monitoring Mechanism Already in Place for Vaccines Less Prone to Parallel Import or Counterfeit

6. For those vaccines that are in general less prone to parallel import or counterfeit, the Government has already put in place a quite comprehensive monitoring mechanism with gatekeeping measures at various levels to ensure the safety and quality of the vaccines. The measures include:

(1) the Pharmacy and Poisons Ordinance ("PPO") and the Pharmacy and Poisons Regulation ("PPR") stipulate that all vaccines must be registered with the Pharmacy and Poisons Board ("the Board") of Hong Kong before being sold or distributed in the territory. This is to ensure that all vaccines meet the prescribed criteria of safety, efficacy and quality;

(2) drug wholesale dealers must be holders of the licence issued by the Board and strictly observe the licencing conditions and the Code of Practice for Holders of Wholesale Dealer Licence to ensure proper handling of vaccines by the wholesale dealers;

(3) in Hong Kong, the import and export of vaccines are regulated by the Import and Export Ordinance ("IEO"). Licensed wholesale dealers must apply to DH for permits when importing/exporting vaccines and ensure that the vaccines match the descriptions in the permits. C&ED is responsible for enforcement actions such as post-shipment verification;

(4) DH monitors the vaccines available in the market in accordance with the PPO and PPR. It also handles complaints and joins forces with C&ED in enforcement operations according to the IEO and the Trade Descriptions Ordinance; and

(5) registered medical practitioners who breach the Code of Professional Conduct and provide unsafe or substandard vaccination service would face disciplinary actions by the Medical Council of Hong Kong.

(II) Inadequate Monitoring for Vaccines with Excessive

Demand in the Past

7. The 2019 incident involving the nine-valent HPV vaccines showed that the authorities' monitoring mechanism for vaccines with excessive demand had been inadequate in the past. The inadequacies, as we notice, fall mainly into three areas: (1) the risk assessment factors under DH's market surveillance mechanism do not include the pharmaceutical product's supply and demand in the market; (2) the laws executed by DH do not target counterfeit vaccines, and DH has no authority to conduct routine inspections at PHFs (including clinics of registered medical practitioners) solely on the ground of investigating counterfeit vaccines; and (3) education and publicity targeted at the main groups receiving the vaccination was insufficient and behind time.

8. Supply of the nine-valent HPV vaccines became tight since 2018. Around mid-2018, a lot of Mainland travellers complained that they could not get vaccinated at PHFs despite having made appointments in advance. DH, however, did not take immediate actions to strengthen monitoring of the nine-valent HPV vaccines provided by PHFs (such as requesting C&ED to conduct more post-shipment verifications on the imported vaccines, or keeping watch on advertisements targeting Mainland travellers who came to Hong Kong for vaccination so as to identify suspicious medical facilities or clinics), or step up publicity and education targeted at the groups taking the vaccination (Mainland travellers in particular). In addition, DH has no authority to conduct routine inspections at the PHFs involved solely for investigating counterfeit vaccines. Criminals then took advantage of the excessive demand in the market to provide parallel imported or counterfeit HPV vaccines.

(III) DH and C&ED Had Taken Prompt Actions in the Wake of the Incidents Involving Nine-Valent HPV Vaccines

9. When complaints involving nine-valent HPV vaccines started to rise significantly in May 2019, DH and C&ED immediately stepped up investigations against PHFs. Between May and September, DH conducted 24.8 investigations and took 20 joint actions with C&ED on average per month and succeeded in raiding several PHFs providing suspected counterfeit or parallel imported nine-valent HPV vaccines. Several people were arrested. Meanwhile, the two departments also implemented a number of strengthened monitoring measures, including conducting special inspections on those licensed wholesale dealers who had imported unregistered nine-valent HPV vaccines for the purpose of re-export; referring all import/export permits already issued involving

unregistered HPV vaccines to C&ED for post-shipment verification, and taking proactive investigations against suspicious PHFs. The number of complaints about nine-valent HPV vaccines plummeted since, and no further breaches of regulations have been found to date. Nevertheless, we must point out that the number of Mainland visitors to Hong Kong has dropped since mid-2019, and the number of people receiving nine-valent HPV vaccination in the territory has declined drastically since the third quarter of that year. The obvious decrease in related complaints during the period might be attributed to the prevailing circumstances, as much as to the actions taken by DH and C&ED.

(IV) The Government Failed to Explain in Detail to Public its Monitoring Mechanism and the Strengthened Monitoring Measures Introduced after the Incidents

10. In the wake of media reports in mid-2019 about PHFs providing allegedly defective nine-valent HPV vaccines, neither FHB nor DH took the initiative to explain in detail to the public the Government's monitoring mechanism for vaccines provided by PHFs or the strengthened monitoring measures introduced in response to those incidents. Although C&ED and DH had issued press releases with respect to the three operations between May and July 2019, they had only briefed the Legislative Council twice with regard to the strengthened monitoring measures newly introduced, and organised briefings for the licensed wholesale dealers directly affected. The general public had received very limited relevant information directly from the Government. Actually, people receiving the vaccination need to know how to protect their own welfare (for instance, by knowing how to find out if the vaccines have been registered and verify the authenticity of the vaccines). An informed and alert general public would also render the Government's monitoring and enforcement efforts much more effective. By announcing the results of this direct investigation, we hope to enhance public understanding of related information, and we urge FHB, DH and C&ED to learn from the experience to improve arrangements for information dissemination.

(V) When the COVID-19 Vaccines Become Available in the Local Private Market, Government Must Keep Relevant Information Accurate and Transparent and Ensure the Vaccines Meet Quality Criteria

11. COVID-19 affects all people in the world and there has been initial success in developing vaccines against it. Vaccination among the general population is expected to help relieve the epidemic.

Recently, some drug manufacturers are already mass-producing the vaccines, and many governments (including that of Hong Kong) have announced their own vaccination programmes. In the early days of rollout, demand for the vaccines will be huge across the globe and in Hong Kong. Information about the supply, safety, efficacy and test results of the vaccines may be quite confusing, or may even lead to misunderstanding and doubts of the general public. Furthermore, while Government-arranged vaccination programmes seem to be the main trend globally at present, it is still possible that drug manufacturers may supply the vaccines to the private markets in individual countries. When that happens, there may be legally imported and parallel imported vaccines, or even counterfeit vaccines in the local private market. FHB and DH must ensure transparency of information about the safety and efficacy of the vaccines, and about the arrangements of the Government's vaccination programme. Besides, they must strengthen the dissemination of accurate information to the public. Should the COVID-19 vaccines become available in the local private market, FHB, DH and C&ED must play the role of gatekeeper properly to ensure that the vaccines taken by members of the public at PHFs meet the quality criteria.

Our Recommendations

12. In the light of our findings and comments above, The Ombudsman makes the following recommendations to FHB, DH and C&ED:

(1) to keep a close watch on the effectiveness of the newly introduced strengthened monitoring measures, and make adjustments or amendments when necessary;

(2) to include the pharmaceutical product's supply and demand in the market as a risk assessment factor under DH's market surveillance mechanism;

(3) to review the information dissemination mechanism. Should serious incidents involving pharmaceutical products occur, they should promptly and proactively explain to the general public their monitoring mechanism, actions taken and the monitoring measures to be introduced so as to allay public doubts; and

(4) to enhance the transparency of information about vaccines newly introduced and proactively provide the

public with information about the safety, efficacy and supply of the new vaccines in a timely manner so that they can understand how to protect their health and welfare.

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